

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT EM-ARC-99-10

OF THE

**U. S. DEPARTMENT OF ENERGY
OFFICE OF WASTE MANAGEMENT**

GERMANTOWN, MARYLAND

MAY 4 THROUGH MAY 7, 1999

Prepared by: _____

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Office of Quality Assurance**

Date: _____

Approved by: _____

**Robert W. Clark
Acting Director
Office of Quality Assurance**

Date: _____

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit EM-ARC-99-010, the audit team determined that the Department of Energy (DOE), Office of Waste Management, EM-30/EM-32/EM-35/EM-37/EM-38, with the exception of the one deficiency, are satisfactorily implementing applicable portions of the QA Program described in the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, and associated Standard Practice Procedures (SPP) for High-Level Waste (HLW). QA Program Elements 1.0, 2.0, 5.0, 6.0, 16.0, 17.0, 18.0, and Appendix A were found satisfactory by the audit team. QA Program Elements 3.0, 4.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0, Supplements I, II, III, IV, V, Appendix B and C were determined not to be applicable to EM-30/32/35/37/38 headquarters HLW activities.

The audit team identified one deficiency during the course of the audit that resulted in the issuance of one new OCRWM Deficiency Report (DR) described in Section 5.5.2 of this report. There were three other deficiencies identified by the audit team that were corrected during the audit. These conditions are described in Section 5.5.4 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and the effectiveness of EM-30/32/35/37/38 in implementing the QA Program as described in the QARD and the EM-30 SPPs for HLW activities.

The following QA Program Elements/Requirements were evaluated during the audit, in accordance with the approved audit plan.

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0	Organization
2.0	Quality Assurance Program
5.0	Implementing Documents
6.0	Document Control
16.0	Corrective Action
17.0	Quality Assurance Records
18.0	Audits
Appendix A	High-Level Waste Form Production

The following QA Program Elements/Requirements were not reviewed during the audit because they are not applicable to the EM-30/32/35/37/38 headquarters scope of work:

3.0	Design Control
4.0	Procurement Document Control
7.0	Control of Purchased Items and Services
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
12.0	Control of Measuring and Test Equipment
13.0	Handling, Storage and Shipping
14.0	Inspection, Test and Operating Status
15.0	Nonconformances
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement IV	Field Surveying
Supplement V	Control of the Electronic Management of Data
Appendix B	Storage and Transportation
Appendix C	Mined Geologic Disposal System

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members and observers and their assigned areas of responsibility:

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements, Technical Areas, Processes, Activities or End-Products</u>
Richard L. Maudlin, Audit Team Leader, Office of Quality Assurance (OQA)	QA Program Elements 2.0, 5.0, 6.0, 18.0 and Appendix A
Gary D. Wood, Auditor, OQA	QA Program Elements 1.0, 2.0, 16.0, and 17.0
Thanhtran Van Ober, DOE/MD-3	Observer

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held at the EM-30/32/35/37/38 offices in Germantown, Maryland, on May 4, 1999. A daily debriefing and coordination meeting was held with the EM-30/32/35/37/38 management, and daily audit team meetings were held to discuss issues and potential deficiencies. The audit was concluded with a post-audit meeting on May 7, 1999. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the pre-audit and post-audit meetings.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, for the program elements that have been implemented, the QA Program is adequate and is being satisfactorily implemented by EM-30/32/35/37/38 for the scope of this audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no stop work orders, immediate corrective actions or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation along with identification of the objective evidence reviewed. The checklists are maintained as QA Records.

5.4 Technical Audit Activities

There were no technical activities evaluated during the audit.

5.5 Summary of Deficiencies

The audit team identified one deficiency during the audit for which one new OCRWM DR has been issued. Three additional deficiencies were identified and corrected during the audit.

A synopsis of the deficiency documented as a DR and the three corrected during the audit are detailed below. The DR has been transmitted under a separate letter.

5.5.1 Corrective Action Requests (CAR)

None

5.5.2 Deficiency Reports

EM-ARC-99-D-061

The organizational structure as defined in SPP 1.02, *Organization*, Revision 2, Figure 1 does not reflect the recent organizational change indicating that the position of HLW QA Program Manager now reports to EM-30 Management.

5.5.3 Performance Reports

None

5.5.4 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only require remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. The “Controlled Distribution Request” for the distribution of DOE/EM/ WO/SPP, Revision 25, and DOE/EM/WO/SPP, Revision 26, did not include or reference a distribution list as required by SPP 6.01, *Distribution of Controlled Documents*, Revision 0. Prior to the completion of the audit, SPP 6.01, Revision 0, IC-0-1 was prepared and approved which changed the requirements to allow for a distribution list to be used which is maintained by document control. The action taken satisfactorily resolves the issue.
2. No objective evidence could be provided to reflect that an “Audit Scope and Planning Document” was prepared and placed in the audit package for EM Internal Audit 99EA-IN-AU-01 as required by SPP 4.02, *Audits*, Revision 2. Prior to completion of the audit, a copy of the “Audit Scope and Planning Document” for the EM internal audit was provided and transmitted to the Central Records Facility for incorporation into the audit records package. The action taken satisfactorily resolves the issue.

3. Internal Audit Report, 99EA-IN-AU-01, was not issued within the 45 days from the date of audit completions as required by SPP 4.02, Revision 2. Prior to completion of the audit, a memo was written to the file which explained the circumstances around a change in organization and responsibilities which prevented the report from being approved and issued. Since the report had been issued, and no other similar conditions of this nature were found, the action taken was considered sufficient to satisfactorily resolved the open issue.

6.0 RECOMMENDATIONS

None

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Result

ATTACHMENT 1

PERSONNEL CONTACTED DURING THE AUDIT

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Meeting</u>	<u>Contacted During Audit</u>	<u>Post-Audit Meeting</u>
Kriss Grisham	HLW QAPM, EM-30	X	X	X
Gerry Camasta	CRF Supervisor, EM-14	X	X	X
Thomas Wright	Engineer, EM-38	X	X	X
Mark Rawlings	WV Team Leader, EM-32	X	X	
Ralph Erickson	Director, EM-32	X	X	X
Kurt Fisher	SR Program Mgr, EM-32	X	X	X
Louis Sirianni	QA Specialist, SAIC	X		
James Antizzo	Director, EM-37			X
James Turi	Associate DAS, EM-30		X	X
Ken Picha	HLW-Type Manager, EM-35	X	X	X
Carl Weber	QA Specialist, RW-3			X
Larry Vaughan	QA Specialist, EM-10			X
Denis Koutsandreas	Engineer, EM-32			X
Thanhtan Van Ober	QA Engineer, MD-3	X		X

ATTACHMENT 2
AUDIT EM-ARC-97-18 DETAIL SUMMARY AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1.0	SPP 1.02, REV. 2	pgs. 1-2	EM-ARC-99-D- 061		SAT	SAT	SAT
2.0	SPP 2.01 REV. 1	pgs. 5-7			SAT	SAT	SAT
	SPP 3.01 REV. 1	pgs. 8-12			SAT	SAT	
	SPP 3.02 REV. 1	pgs. 13-15			SAT	SAT	
	SPP 8.01 REV. 0	pgs. 3-4			SAT	NI	
5.0	SPP 4.04 REV. 2	pgs. 22-26			SAT	SAT	SAT
6.0	SPP 6.01 REV. 0	pgs. 27-28	CDA# 1		SAT	SAT	SAT
16.0	SPP 5.01 REV. 0	pgs. 29-30			SAT	SAT	SAT
	SPP 5.02 REV. 0	pg. 20-21			SAT	NI	
17.0	SPP 7.01 REV. 1	Pgs. 31-34			SAT	SAT	SAT
18.0	SPP 4.01 REV. 0	pgs. 35-36			SAT	SAT	SAT
	SPP 4.02 REV. 2	pgs. 37-40	CDA# 2 & 3		SAT	SAT	
	SPP 4.03 REV. 0	pgs. 16-19			SAT	SAT	
APPEND. A	MOA 05/23/95	pgs. 41			SAT	NI	SAT

LEGEND:

CDA	Corrected During Audit
NI	Not Implemented
SAT	Satisfactory